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09/601,267	08/25/2000	William Nicol Keith	9013-18	9771

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EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/601,267

Applicant(s)

KEITH, WILLIAM NICOL

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 28-44 is/are pending in the application.
- 4a) Of the above claim(s) 29 and 32-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4 is/are rejected.
- 7) ☒ Claim(s) 2,3,5-10,28,30 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/28/00 & 7/14/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

FINAL ACTION

1. Applicant's amendment filed June 1, 2004 is acknowledged and has been entered. Claim Claims 1-10 have been amended. Claims 11-27 have been canceled. Claims 29-44 have been added. Claims 1-10 and 28-44 are pending.

2. Newly submitted claims 29 and 32-44 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims 29 is drawn to a method for the treatment of cancer. The claim 29 contains the subject matter of the original claims 24 and 25 that were restricted in the Office action mailed on November 5, 2001. The claims 32-44 are directed to a mouse telomerase RNA as shown in fig 4b (SEQ ID NO: 37) and method of treating cancer. The promoter sequence from the mouse gene was not previously presented or searched in the previous Office action. The isolated promoter sequence from the mouse telomerase RNA (SEQ ID NO: 37) is both structurally and functionally distinct from the isolated promoter sequence of the human telomerase RNA. Likewise, a search of the different sequence from the mouse and the human telomerase RNA are not coextensive because literature that present the human telomerase RNA sequence will not present the mouse telomerase sequence because the different promoter sequence can function irrespective of each other. Searching the claims 32-44 with the elected claims 1-10 and new claims 28, 30 and 31 together would constitute a burden to the examiner because the claims contain non-overlapping subject matter.

3. Since applicant has received an action on the merits for the originally presented invention drawn to an isolated promoter sequence for the human telomerase RNA as shown in Fig. 4a, this invention has been constructively elected by original presentation for prosecution on the merits.

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Accordingly, claims 29 and 32-44 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. The claims 1-10, 28, 30 and 31 are discussed in this Office Action.

4. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Objections and Rejections

6. The objections to the specification are withdrawn in view of Applicant's amendment to the specification. The objections to the claims are withdrawn in view of Applicant's cancellation of the claims. The claim rejection under 35 USC 101/112 is withdrawn in view of Applicant's cancellation of the claims. The claim rejection under 35 USC 112 first paragraph as lacking enablement and written description is withdrawn in view of Applicant's amendment and cancellation of the claims. The claim rejection under 35 USC 112 second paragraph is withdrawn in view of Applicant's amendment and cancellation of the claims. The prior art rejections under 35 USC 102(b) is withdrawn in view of Applicant's amendment and cancellation of the claims. The prior art rejection under 35 USC 102(a) is withdrawn in view of Applicant's submission of priority document which establishes priority prior to March 1998.

Drawings

7. The submission of a formal drawing for Fig. 4B filed on July 14, 2003 is acknowledged and has been entered.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

Claim Rejections - 35 USC § 112: lack of adequate written description

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim 4 is drawn to an isolated promoter sequence according to claim 1 having the sequence as shown in Fig 4a (SEQ ID NO: 36) modified by insertion, addition, deletion, or substitution of one or more nucleotides wherein said modified promoter has at least 60% homology over at least 40 nucleotides of said isolated promoter sequence of claim 1. The claim as written encompasses a large genus of nucleic acid species not adequately described or disclosed. The specification teaches at page 6 that smaller portions of the nucleotide sequence may be used as long as the promoter activity is retained. The specification teaches that the fragments being 200 nucleotides or fewer in length are encompassed by the invention. At page 9, the specification teaches that

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promoter which has a sequence that is a fragment, mutant, allele, derivative or variant, by way of addition, insertion, deletion or substitution of one or more nucleotides, of the sequence of the hTR promoter shown in figure 4a having at least 60% homology, preferably at least about 70% homology, more preferably at least about 80% homology, more preferably at least about 90% and most preferably at least about 95% homology are encompassed by the instant invention. At page 45, the specification teaches that a minimum promoter sequence can be defined as extending 272 bp upstream of the transcription start site, and that elements responsible for promoter activity must be contained in a 231 base pairs region between -272 bp and -42 bp.

The specification does not describe or disclose any functionality of the undisclosed nucleic acid molecules associates with a sequence having only at least 60% homology over at least 40 nucleotides of the isolated promoter sequence as shown in SEQ ID NO: 36 and being modified by insertion, addition, deletion or substitution of one or more nucleotides. In fact the specification makes clear that for minimal promoter activity a region containing at least a 231-basepair region between -272 bp and -42 bp must be present. The scope of the claim 4 includes numerous structural variants thereof, and the genus is highly variable because a significant number of structural differences between genus members is permitted which is neither described nor disclosed. Likewise the specification or claims do not describe or provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the

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genus, and because the genus is highly variable, SEQ ID NO: 36 alone is insufficient to describe the genus. A representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus applicant was not in possession of the claimed genus.

Claim Objections

10. Claims 9, 10 and 28 are objected to because of the following informalities: For clarity and precision of claim language, it is suggested amending the claims 9, 10 and 28 to recite "isolated host cell" because the claims currently read on whole mammalian organisms, such as humans. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(a) Claim 1 lacks proper antecedent basis for "said hTR gene" because the previous limitations do not recite "hTR gene" but recites "(hTR)". It is suggested inserting "gene" after "(hTR)" in line two such that the claim language agree.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Villeponteau et al (US 5,583,016, December 10, 1996). Regarding claim Villeponteau et al teach an isolated promoter sequence having the sequence as shown in fig 4a modified by either addition or deletion or substitution of one or more nucleotides, wherein said modified promoter has at least 60% homology over at least 40 nucleotides of said isolated promoter sequence of claim 1 (*Note* Villeponteau teaches a sequence having 97% homology to the sequence of SEQ ID NO: 36*) (see SEQ ID NO: 3, col. 8-11, see also col. 18, lines 66-67 to col. 19, lines 1-21).

Conclusion

15. Claims 1 and 4 have been rejected. Claims 2, 3, 5, 6-10, 28, 30 and 31 are objected because they depend from rejected claims. Claims 9, 10 and 28 have been also been objected for the reasons noted above. The claims 1-3, 5-10, 28, 30-31 have not been rejected under prior art because no prior art could be found teaching an isolated promoter sequence for the human telomerase RNA (hTR gene) comprising the sequence of SEQ ID NO: 36 which initiates transcription of DNA operably linked downstream of said promoter. The closest prior art,

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Villeponteau teaches a sequence having about 97% homology to the sequence of SEQ ID NO: 36.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/9/05